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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|-----------------------|------------------|
| 10/729,146 | 12/04/2003 | Timothy A. Ringeisen | KN P 0146 | 1356 |
| 42016 | 7590 | 12/04/2008 | EXAMINER | |
| KENSEY NASH CORPORATION | | | ROGERS, JAMES WILLIAM | |
| 735 PENNSYLVANIA DRIVE | | | | |
| EXTON, PA 19341 | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/729,146 | RINGEISEN ET AL. | |
| | Examiner | Art Unit | |
| | JAMES W. ROGERS | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 September 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 22-26,28-33,36-50,52-87 and 90-95 is/are pending in the application.

4a) Of the above claim(s) 66-73,91 and 92 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 22-26,28-33,36-50,52-65,74-87,90 and 93-95 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicants amendments to the claims filed 09/12/2008 have been entered. Any objection/rejection from the previous office action filed 05/09/2008 not addressed below has been withdrawn.

Specification

The amendment filed 09/12/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "Regardless of the method of compression, it never involves any rotation of any piston, plate or mold".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-26,28-30,36-38,42-45,47-50,52-65,74-75,77-79,94 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 22 and 42 now recite the new limitation that a compressive force of a magnitude of at least 0.2 ton per square inch is applied; there is inadequate support within the specification for this new limitation. Applicants do have

support for a compressive force of 0.01 to 100 tons/square inch or 0.2 to 2.0 tons/square inch. However the ranges above do not support a range starting from 0.2 tons/square inch with an open ended upper limit (essentially limitless).

Response to Amendment

The declaration under 37 CFR 1.132 filed 09/12/2008 is insufficient to overcome the §102(b) and §103(a) rejections based upon Stone (5,158,574), Li (US 2002/0127270) and Haldimann (US 6,428,576 B1) as set forth in the last Office action because: firstly the SEM photomicrograph of the material shown in appendix A is only said to resemble the material of Li, however this material was not described as being formed by the process of Li, thus the declaration is essentially an opinion that the material of Li should look like the SEM photomicrograph in appendix A. Applicants assert that the plates of Li and the fissures or fluid planes extended uninterrupted across the photo and this is in contrast to applicants material shown in appendix C which is said to be interrupted by fissures. The examiner disagrees with this characterization, the issue at hand is essentially if the fissures of Li are random, on looking at the material said to resemble the Li reference there appears to be random fissures or holes located throughout the plates. In essence applicants claimed invention is not seen as precluding the material shown as Li even though it is just an opinion that such a material represents the teaching of Li. Furthermore applicant's opinion that the rotating mandrel of Stone would disrupt any organization into plates and the claimed invention never features a rotating piston during the processing step is not found persuasive. It was previously noted by the examiner that the declaration of Mr.

Ringeisen was an opinion type of declaration and did not show any data to support the conclusion that compression as taught within Li or Stone would not lead to at least some orientation of the fibers and the formation of at least some plates. Since we are discussing the claimed product we must compare the implants described in the art with applicants claimed invention. The limitations that the implants comprise fibers, which are at least partially aligned into a plurality of plates, is simply not found very limiting by the examiner. Since the cited Stone and Li references describe implantable fibers, which are produced by compressing it is inherent that the fibers must at the very least form some plates of at least some of the fibers when they are compressed.

Response to Arguments

Claims 39 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the previous office action filed 05/09/2008.

Applicant's arguments filed 09/12/2008 have been fully considered but they are not persuasive.

Applicants assert that there is inherent support for the limitation that the compressing force is exclusive of any rotation of a piston or mold since the specification did not suggest or disclose a rotating mold or piston and the declaration of co-inventor Timothy Ringeisen also stated such.

The examiner disagrees, in order to exclude an element from the claimed invention it at least had to be conceived or mentioned within the specification as originally filed.

Claims 22-26,28-33,36-41,74-77,80-81,84,87, 90 92-93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574), for the reasons set forth in the previous office action filed 05/09/2008.

Claims 22-26,28-30,36-38,42-45,47-48,52-65,74-84,87,92-93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270), for the reasons set forth in the previous office action filed 05/09/2008.

Claims 22-26,28-33,36-50,52-65,74-87,90 and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574) in view of Li et al. (US 2002/0127270) and in further view of Haldimann (US 6,428,576 B1, disclosed previously), for the reasons set forth in the previous office action filed 05/09/2008.

Applicant's arguments filed 09/12/2008 have been fully considered but they are not persuasive.

Applicants assert that all independent claims except 39 and 42 require a plurality of plates of at least partially aligned fibers that contain a space between the plates that are fluid planes that are located randomly throughout the structure of the device and this limitation is not taught by any of the cited references above.

The examiner as stated above and previously does not find this argument persuasive. The limitations that the implants comprise fibers, which are at least partially aligned into a plurality of plates, is simply not found very limiting by the examiner. Since the cited Stone and Li references describe implantable fibers, which are produced by compressing it is inherent that the fibers must at the very least form some plates of at least some of the fibers when they are compressed. Also at least Li states that the

orientation of the fibers is in one direction, thus meeting the limitation of at least partial alignment.

Applicants further assert that in regards to independent claim 31 none of the references describes location specific crosslinking.

The examiner respectfully disagrees. Stone clearly teaches that the GAG crosslinkers employed may be concentrated at different areas including points of high stress, typically the distal regions (14 and 16 in Fig 1) and less concentrated at the central region (12 in Fig 1), the distal region is periphery to the central region, therefore the limitation is met.

Applicants assert that none of the references cited above teach the claimed implantable device of claims 39 and 90 which are non-crosslinked.

The examiner respectfully disagrees, at least within Stone it is said that at least a portion of the fibers **may** be crosslinked, thus this step is clearly optional. See abstract of Stone

Applicants further assert that none of the references cited above teach each plate being independent of the orientation of fibers within adjacent plates as required within claim 42.

Li teaches a method of fabricating multiple layer membrane (meeting multiple plates) the layers are preferably oriented in different directions, thus meting the limitation

Applicants lastly assert that none of the references above teach the new limitation within claims 22 and 42 on the compressive force being at least 0.2 tons/square inch.

The relevance of this assertion is unclear. As noted above this new limitation is new matter and is a product by process type of limitation; since the claimed material is within the scope of the cited references applicants claims are anticipated and obvious by the references cited above. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Conclusion

No claims are allowed at this time.

Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618